510(k) Summary K042667

Applicant's Name

Yoram Levy
Consultant

Galil Medical Ltd.
P.O. Box 224
Yokneam Industrial Park 20692
ISRAEL
Telephone: 972-4-959 10 80
Fax: 972-4-959 10 77

Contact Person:

Yoram Levy, QSite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

B. Trade Name:

SeedNetGold™ with Renal Kit

E. Classification:

Classification name: Cryosurgical unit
Common/usual name: Cryosurgical unit with argon-cooled probes
Product Code: GEH
Regulation No.: 878.4350

F. Reason for the Premarket Notification Submission:

Galil Medical intends to market a Renal Kit that includes cryoneedles, thermal sensors, and a cryoneedle insertion template for use with the SeedNet Gold during renal cryoablation.

F. Identification of Legally Marketed Predicate Devices:

Galil's SeedNetGold™

F. Performance Standards or Special Controls:

The SeedNet™ and the SeedNetGold™ conform to ASTM Designation F 882-84 (re-approved 1996).
The SeedNet™ and the SeedNetGold™ conform to ANSI/AAMI/ISO 11135.

Indications for Use:

The SeedNetGold™ with Renal Kit is intended for cryogenic destruction of tissue during surgical procedures. The SeedNetGold™ with Renal Kit is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

The SeedNetGold™ with Renal Kit has the following specific indications:

- Urology (ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia "BPH")
- Oncology (ablation of cancerous or malignant tissue and benign tumors, and palliative intervention)
- Dermatology (ablation or freezing of skin cancers and other cutaneous disorders. Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas small hemanglomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratoses, cavernous hemanglomas, perianal condylomata, and palliation of tumors of the skin)
- Gynecology (ablation of malignant neoplasia or benign dysplasia of the female genitalia)
- General surgery (palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions.)
- ENT (Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth).
- Thoracic surgery (ablation of arrhythmic cardiac tissue cancerous lesions)
- Proctology (ablation of benign or malignant growths of the anus or rectum, and hemorrhoids)

The SeedNetGold™ System may be used with a magnetic resonance imaging (MRI) device or an ultrasound device to provide real-time visualization of the cryosurgical procedure.

Technological Characteristics:

The SeedNetGold™ with Renal Kit is the exact same device as the cleared SeedNetGold™ (K031117), except for the Renal Kit, which is a modification to the SeedNet Gold's cleared Prostate Kit and Prostate Template.

Performance Testing

Bench testing demonstrated that the SeedNetGold™ with Renal Kit is at least as safe and effective as the cleared SeedNetGold™ with the Prostate Kit and Prostate Template in destroying tissue by the application of extreme cold temperatures during cryosurgical procedures.

Comparison to the Predicate Device

The SeedNetGold™ with Renal Kit has the same intended use, general and specific indications, and principles of operation as the cleared SeedNetGold™. In addition, the SeedNetGold™ with Renal Kit has the exact same technological characteristics as the cleared SeedNetGold™, except for their Renal Kit, which is an optional accessory. The minor differences between the Renal Kit and the Prostate Kit and Prostate Template, do not raise new questions of safety or effectiveness. Bench data demonstrates that the SeedNetGold™ with Renal Kit is as safe and effective as the cleared SeedNetGold™; thus, the SeedNetGold™ with Renal Kit is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Galil Medical Ltd.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson LLP
555 Thirteenth Street NW
Washington, DC 20004

Re: K042667
Trade/Device Name: SeedNetGold™ with Renal Kit
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II (two)
Product Code: OCL, GEH
Dated: September 7, 2004
Received: September 29, 2004

Dear Mr. Kahan:

This letter corrects our substantially equivalent letter of October 14, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K043667

Device Name: SeedNetGold™ with Renal Kit

Indications for Use:

The SeedNetGold™ with Renal Kit is intended for cryogenic destruction of tissue during surgical procedures.

It is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

- The SeedNetGold™ with Renal Kit System (SeedNetGold™ System) has the following specific indications:
- Urology (ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia "BPH")
- Oncology (ablation of cancerous or malignant tissue and benign tumors and palliative intervention)
- Dermatology (ablation or freezing of skin cancers and other cutaneous disorders.
- Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas small hemanglomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratoses, cavernous hemanglomas, perianal condylomata, and palliation of tumors of the skin)
- Gynecology (ablation of malignant neoplasia or benign dysplasia of the female genitalia)

K042667 2/2

- General surgery (palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions.)
- ENT (Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth).
- Thoracic surgery (ablation of arrhythmic cardiac tissue and cancerous lesions,)
- Proctology (ablation of benign or malignant growths of the anus or rectum and hemorrhoids)

The SeedNet™ System (SeedNetGold™ System) may be used with a magnetic resonance imaging (MRI) device or an ultrasound device to provide real-time visualization of the cryosurgical procedure.

Prescription Use __x__ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

510(k) Number

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042667